From: <u>Bill Jacobs</u>
To: <u>Anie Lauzon</u>

Cc: <u>Dan Peacock</u>; <u>Russell Wasem</u>

Subject: Re: Fw: PMRA inquiry - Rodenticide bait stations

Date: 07/18/2011 11:22 AM

Attachments: pic00137.gif

I was not able to open the attachment to your note.

I have not reviewed data on many of the bait station products registered pursuant to the 2008 Risk Mitigation Decision (RMD) for rodenticides, but have had extensive involvement with rodenticide bait stations for the past 28 years. It is possible that Jennifer Gaines, who is out this week, reviewed the specific product about which you are asking.

Our basic requirements for registering ready-to-use rodenticide baits stations are essentially as described in the RMD. (We can answer specific questions about nuances of test protocols.) In general, the list of 3 items of evidence that you mention would not qualify a bait station for Tier 1, 2, or 3 because no reference to tamper-resistance testing with children or dogs is included. The adult test that you mention is needed only for refillable bait stations, which could be Tier 1, 2, or 3 depending upon the results of the dog and child tests and whether there was a determination of weather-resistance. If the applicant has not mentioned dog and child studies, it might be that they were not performed or were not passed.

In your situation, I would require submission of whatever information you conclude is needed to support a Canadian registration and the labeling that is proposed for the product. If you are not comfortable relying upon the applicants' attestations, ask for the supporting data. If you want an example of the station itself to be submitted, request it. If you want to see efficacy data on the ready-to-use bait station product, request them. You should become comfortable that the product proposed for registration meets the relevant requirements under Canada's laws.

▼ Fw: PMRA inquiry - Rodenticide bait stations

Fw: PMRA inquiry - Rodenticide bait stations

Anie to: Bill Jacobs 07/18/2011
Lauzon 09:34 AM

Hello Bill,

I had sent the following question to Dan Peacock, but Rusty recommended I contact you instead.

I have a question with regards to the review of data submitted in support of tamperproof bait stations for rodenticides. Specifically, I wanted to confirm that the EPA has received and reviewed the following data (required in the EPA decision document) for Tier 1 bait stations it found acceptable:

- 1 Description of weather-resistant properties
- 2 Reports and raw data from studies conducted according to the USEPA protocol METHOD FOR TESTING READY-TO-USE BAIT STATIONS WITH ADULTS FOR FACILITY OF OPENING, RECLOSING, AND SECURING
- 3 Drawings of bait station design

The PMRA is currently reviewing a data package submitted to the PMRA by a US & Canadian registrant. Since this registrant has products with Tier 1 bait stations approved in the US, I suspect the EPA has received and reviewed the same package. The package did not however include the data outlined above.

Since the PMRA requirements (REV 2010-17, *Risk Mitigation Measures for Eight Rodenticides*) were consistent with the EPA requirements outlined in the *Risk Mitigation Decision for Ten Rodenticides* document, I wanted to confirm that the EPA requirements have not changed, and that this data, in particular the test data, is required in the US.

Please do not hesitate to give me call if you have any question, or need more information.

Thank you for your assistance.

Regards, Anie

Anie Lauzon Scientific Evaluation Officer / Agent d'Évaluation Scientifique PMRA, Health Canada / ARLA, Santé Canada 2720 Riverside Drive C359 P.L. 6603C Ottawa, ON K1A 0K9 Phone: (613) 736-3396

---- Forwarded by Anie Lauzon/HC-SC/GC/CA on 18/07/2011 09:29 AM -----

From: Russell Wasem < Wasem.Russell@epamail.epa.gov>

To: Anie Lauzon <anie.lauzon@hc-sc.gc.ca>

Date: 18/07/2011 09:24 AM

Subject: Re: PMRA inquiry - Rodenticide bait stations

Good Morning Anie,

Try following up with Bill Jacobs (jacobs.bill@epa.gov) in Dan's branch. Dan wrote all of the testing protocols for rodent bait stations and I believe he currently reviews all of the testing data submitted to support the bait stations. He is an incredible resource in this area.

Rusty		
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From: Anie Lauzon <anie.lauzon@hc-sc.gc.ca>
To: Dan Peacock/DC/USEPA/US@EPA

To: Dan Peacock/DC/USEPA/US@EPA Cc: Russell Wasem/DC/USEPA/US@EPA

Date: 07/15/2011 09:20 AM

Subject: Re: PMRA inquiry - Rodenticide bait stations

Good morning Dan,

I wanted to follow up on this inquiry.

Best Regards, Anie

Anie Lauzon Scientific Evaluation Officer / Agent d'Évaluation Scientifique PMRA, Health Canada / ARLA, Santé Canada 2720 Riverside Drive C359 P.L. 6603C Ottawa, ON K1A 0K9 Phone: (613) 736-3396 anie.lauzon@hc-sc.gc.ca

(Embedded image moved to file: pic00137.gif)Inactive hide details for Anie Lauzon---05/07/2011 11:31:34 AM---Hello Dan, I have another question for you, with regards to thAnie Lauzon---05/07/2011 11:31:34 AM---Hello Dan, I have another question for you, with regards to the review of data submitted in support

From: Anie Lauzon/HC-SC/GC/CA
To: Peacock.Dan@epamail.epa.gov

Date: 05/07/2011 11:31 AM

Subject: PMRA inquiry - Rodenticide bait stations

Hello Dan,

I have another question for you, with regards to the review of data submitted in support of tamper-proof bait stations for rodenticides. Specifically, I wanted to confirm that the EPA has received and reviewed the following data (required in the EPA decision document) for Tier 1 bait stations it found acceptable:

1 - Description of weather-resistant properties

2 - Reports and raw data from studies conducted according to the USEPA protocol METHOD FOR TESTING READY-TO-USE BAIT STATIONS WITH ADULTS FOR FACILITY OF OPENING, RECLOSING, AND SECURING

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Thank you for your assistance.

Regards, Anie

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anie.lauzon@hc-sc.gc.ca(See attached file: pic00137.gif) pic00137.gif